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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,847	03/17/2004	Thomas Hermann	250350US	3961
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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KIM, ALEXANDER D	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,847	<b>Applicant(s)</b> HERMANN ET AL.	
	<b>Examiner</b> Alexander D. Kim	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/058,945.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/17/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>alignments, taxonomy.</u>              |

## **DETAILED ACTION**

### ***Application Status***

1. By virtue of a preliminary amendment filed on 8 June 2004, claims 1-45 have been canceled; and claims 46-65 has been amended. Thus, claims 46-65 are pending in this instant case.

### ***Priority***

2. The application claim for benefit of a prior-filed application 10/058945 filed 30 January 2002, under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c), noted in the transmittal and the amended first page of the specification is acknowledged.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/058,945 filed on 30 January 2002. This foreign priority is in German, without English translation.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) filed on March 17, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

***Objections to the Specification***

4. The specification is objected to because the title is not descriptive of the elected claims. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The examiner suggests the following new title, for example:

---A process for L-amino acid preparation by Coryneform bacterium with reduced level of otsA gene---

5. The Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 08.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the full name of the enzyme (trehalose 6-phosphate synthase) and the source species (*Corynebacterium glutamicum*) for completeness.

***Claim Objections***

6. Claim 61 is objected to because of the following informalities: The claim 61 contains typographical error in "acteoglutamicum"; the appropriate spelling is ---acetoglutamicum---. Appropriate correction is required.

7. Claim 62 is objected to because of the following informalities: The "and" is missing at the end of a list.

8. Claims 62 and 64 are objected to because of the following informalities: The period at the end of claim is missing. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 62 is rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 62 recites the limitation "code for lysine export" at the end of claim; however a gene cannot code for a function. Clarification is required.
10. Claims 62 and 64 are rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 62 and 64 recite the limitation "the Zwa1 protein" and "the Zwa2 protein", respectively. There is insufficient antecedent basis for this limitation in the claim. It is unclear if the claims are limited to the one species of each disclosed in the specification (see page 26-27). With regard to claim 64, limiting to decreasing only the *Corynebacterium glutamicum* species of zwa2 would

Art Unit: 1656

be further confusing since all Coryneform are encompassed and not just

*Corynebacterium glutamicum*. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 49, 50, 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to reducing *otsA* gene expression or reducing the activity of trehalose 6-phosphate synthase at least 5% or 10% compared to an unmodified Coryneform bacterium which limitations are not supported by the original disclosure. The applicant is advised to point out the support in the original disclosure or amend the instant claims.

12. Claims 46 and 54-65 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. The instant claims are drawn to the process for preparing L-amino acids using reduced activity trehalose 6-phosphate synthases.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. (*Enzo Biochem* 63 USPQ2d 1609 (CAFC 2002)).

The instant specification suggests reducing trehalose 6-phosphate synthases catalytic properties (page 20 §3) by mutations; however no specific reduced activity trehalose 6-phosphate synthases are disclosed. The specification also teaches a deletion of the *otsA* gene, which host cell now has no trehalose 6-phosphate synthase activity. However, this *otsA* deletion mutant is not adequate to disclose the common structural characteristics of claimed genus to correlate the structures and functions of

Art Unit: 1656

reduced activity trehalose 6-phosphate synthase. The specification does not indicate prior art that disclose trehalose 6-phosphate synthases with reduced catalytic activity. Because there is neither a single example of a reduced activity trehalose 6-phosphate synthase nor sufficient description representing the genus claim of trehalose 6-phosphate synthases, one skilled in the art would be unable to make and use the claimed invention by correlating the structure and/or the function of other members of trehalose 6-phosphate synthases.

13. Claims 62 and 63 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to methods using a lysC, which codes for a feed-back resistant aspartate kinase.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent



Art Unit: 1656

said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (Enzo Biochem 63 USPQ2d 1609 (CAFC 2002)).

The instant specification teaches the enhancement, in particular over-expression of a *lysC*, which codes for a feed-back resistant aspartate kinase (see page 26). The over-expression of a gene in the bacteria by recombinant technique is a one of techniques well known in molecular biology and many cloning systems are available for over-expression. However, this recombinant technique requires sufficient genetic information about structure and function correlation to be performed by one skilled in the relevant art. Because, *lysC* codes for both non feed-back resistant aspartate kinases as well as feed-back resistant aspartate kinases in the art, the disclosure of information about the structure and function correlation is needed to practice the claimed invention of a feed-back resistant aspartate kinase. The single feed-back resistant aspartate kinase species disclosed in the specification does not adequately represent structure of the genus of all feed-back resistant *lysC* and how they would correlate to their function. Therefore, one skilled in the relevant art would be unable to make and use the claimed invention by virtue of the instant disclosure.

Art Unit: 1656

14. Claims 62-64 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims 62 and 63 are drawn to method involved in an increased amount of "the Zwa1 protein" and/or a lysE; the instant claim 64 is drawn to method involved in a decreased amount of "the Zwa2 protein".

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (*Enzo Biochem* 63 USPQ2d 1609(CAFC 2002)).

The instant specification discloses a process using increased amounts of the Zwa1 and a lysE gene products. The specification also discloses a process using decreased amounts of the Zwa2 product (see pages 25-26). The change of the gene product by recombinant modification has been known for long time and the recombinant method to increase or decrease in the gene product is also well known to one skilled in the art. There are many promoters and repressors to be used in the gene products regulation. However, sufficient knowledge about correlation between structure and function of a gene is required to practice recombinant modification. Species of the Zwa1, lysE and the Zwa2 gene disclosed in the specification do not adequately represent the common structural characteristics of genera of the Zwa1, lysE and the Zwa2 to correlate to their function. Therefore, one skilled in the relevant art would be unable to make and use the claimed invention by virtue of the instant disclosure from the specification.

15. Claims 46-53 and 60-65 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for a reduction or a decrease in Coryneform bacterium gene expression by recombinant modification, does not reasonably provide enablement for a reduction of Coryneform bacterium gene expression by a "suitable culturing" as described in Specification, page 20. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The nature of invention is drawn to a process of the reduction in gene expression by suitable culturing. However, applicants disclose no direction or guidance as to how to make the suitable culturing condition. The instant specification also does not disclose a single working example of reduction in gene expression by suitable culturing. Additionally, the prior art is silent about general culture conditions suitable to reduce the gene expression. Moreover, the unpredictability of reducing gene expression by

Art Unit: 1656

suitable culturing is high. For all of the above reasons, it would require undue experimentation necessary to practice the full scope of the claimed methods. To overcome this rejection, the examiner suggests requiring a recombinant modification of Coryneform bacteria wherein said modification results in a reduction of *otsA* gene expression, for example.

16. Claim 46 and 54-65 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for using Coryneform bacterium with reduced trehalose 6-phosphate synthase activity by virtue of an *otsA* deletion (see pages 37-44, Example 3-4), does not reasonably provide enablement for methods using a trehalose 6-phosphate synthase with reduced catalytic activity. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use of the invention commensurate in scope with these claims. Claims 54-59 lack enablement to the full extent of their scope because said claims are limited to methods using trehalose 6-phosphate synthase with reduced catalytic activity. The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* above.

The nature of the invention is drawn to a method using trehalose 6-phosphate synthases with reduced catalytic activity. However, applicants disclose no direction or guidance on what mutation(s) would result in a reduction of catalytic activity. The specification also failed to disclose any working example of trehalose 6-phosphate synthases with reduced catalytic activity. Additionally, the prior art does not teach as to

Art Unit: 1656

how to reduce catalytic activity in any trehalose 6-phosphate synthases. Because of the complex nature of enzyme catalysis and number of amino acids involved in catalysis, the unpredictability of reducing a catalytic activity of trehalose 6-phosphate synthase is high. For all of the above reason, it would require undue experimentation necessary to practice the full scope of the claimed methods.

17, Claims 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using an increased amount of any aspartate kinase, does not reasonably provide enablement for methods using an increased amount of feedback resistant aspartate kinases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* described above.

The nature of the invention is drawn to a process using only a feedback resistant aspartate kinase specifically (see page 25-26). However, lysC encodes both non-feedback resistant aspartate kinases and feedback resistant aspartate kinases. Because feedback resistance is not an engineered characteristic but native to aspartate kinase disclosed in the instant claim, it would be unpredictable to make any other lysC product to become a feedback resistant. Applicants disclose no direction or guidance as to how to make any lysC to become feedback resistant. The specification also does not disclose a single working example of making an aspartate kinase to become feedback resistant.

Art Unit: 1656

Additionally, the prior art is silent about making a *lysC* to become a feedback resistant aspartate kinase. Moreover, the unpredictability of making a feedback resistant aspartate kinase from any *lysC* is high. For all of the above reasons, it would require undue experimentation necessary to practice the full scope of the claimed methods.

18, Claims 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for method using an increased amount of *Corynebacterium glutamicum* <sup>*lysE*</sup>~~*lysC*~~ and *zwa1*, does not reasonably provide enablement for method using an increased amount of gene products for any *lysE* and *zwa1*. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* described above.

The nature of invention is drawn to a process using increased amount of any *lysE* and/or *zwa1* gene product. However, the specification has no description on the genus *lysE* and *zwa1* in order to make and use claimed invention. The applicants disclose only a single example of each without any direction or guidance as to how to increase of any other *lysE* and *zwa1*. The prior art also does not describe the genus *lysE* and *zwa1*. Additionally, without the knowledge of the genus *lysE* and *zwa1*, increasing any *lysE* and/or *zwa1* gene product is unpredictable. For all of the above

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reasons, it would require undue experimentation necessary to practice the full scope of the claimed methods.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Tzvetkov et al. (Microbiology (July 2003), 149, pp 1659-1673). Claims 49 and 50 are considered a new matter in this instant office action as previously described in rejection 112, 1<sup>st</sup>. Thus, the priority date for claims 49 and 50 is the instant application's filing date, March 17, 2004. In the instant case, Claims 49 and 50 are drawn to a process for preparing L-amino acids using a recombinant modified *Corynebacterium* with an *otsA* expression is reduced at least 5% and at least 10%, respectively.

Ohtaki et al. teach that disrupting the gene coding for trehalose-6-phosphate synthase, preferably by deletion, in *Corynebacterium* leads to an accumulation of



Art Unit: 1656

amino acid, specifically L-Glu, in the medium (see Abstract). Deletion inherently results in expression reduced by 100% with respect to wild-type. Ohtaki et al. also teach a process of collecting amino acid and a process of measuring L-Glu accumulation "in the medium" (see Abstract and see Example 3, §0123, page 7). Thus, Ohtaki et al. teach processes that meet all the limitation of the instant claims.

20. Claim 46-48, 51-53, 60-62 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Ohtaki et al. (USPAP 2002/0137150 filed on 2 Jul. 2001 as cited in IDS). The instant claims are drawn to a process for preparing L-amino acids using *Coryneform* bacterium with reduced level of the *otsA* gene product.

Ohtaki et al. teach that disrupting the gene coding for trehalose-6-phosphate synthases, preferably by deletion, in *Coryneform* bacterium leads to an accumulation of amino acid, specifically L-Glu, in the medium (see Abstract). Deletion inherently results in expression reduced by 100% with respect to wild-type. Ohtaki et al. also teach a process of collecting amino acid and a process of measuring L-Glu accumulation "in the medium" (see Abstract and see Example 3, §0123, page 7). Ohtaki et al. teach that amino acid production can be carried out with the group of microorganisms such as *Corynebacterium glutamicum* (§0037), *Corynebacterium acetoglutamicum* (§0034), *Corynebacterium acetoacidophilum* (§0033) or *Corynebacterium thermoaminogenes* (§0040) (see the list on page 2). The *Brevibacterium flavum* in claim 61 is a synonym of *Corynebacterium glutamicum*. Finally, Ohtaki et al. teach production of amino acids by *Corynebacterium* with enhanced activity of enzymes in addition to the deletion or

Art Unit: 1656

decrease of trehalose synthesis such enzymes are glyceraldehydes 3-phosphate dehydrogenase (*gap*), triose phosphate isomerase (*tpi*) or pyruvate carboxylase (*pyc*) (see page 4 §0093). The *otsA* sequence taught by Ohtaki et al. has a gene sequence with high similarity to SEQ ID:1 in the instant application (see attachment, 99.7% local similarity) and thus would hybridize under the prescribed stringent condition. Thus, Ohtaki et al. teach processes that meet all the limitation of the instant claims.

21. Claims 49 and 50 are rejected under 35 U.S.C. 102(a) as being anticipated by Tzvetkov et al. (Microbiology (July 2003), 149, pp 1659-1673). Claims 49 and 50 are considered a new matter in this instant office action as previously described in rejection 112, 1<sup>st</sup>. Thus, the priority date for claims 49 and 50 is the instant application's filing date, March 17, 2004. In the instant case, Claims 49 and 50 are drawn to a process for preparing L-amino acids using a recombinant modified *Corynebacterium* with an *otsA* expression is reduced at least 5% and at least 10%, respectively.

Tzvetkov et al. teach a recombinant modified *Coryneform* bacterium with deletion of the gene encoding trehalose 6-phosphate synthases (*otsA*) (see Abstract), which meets the limitation of the *otsA* gene product is "reduced at least 5%" and "reduced at least 10%" because deletion inherently reduce by 100%. Tzvetkov et al. also describe teachings that show steps of *otsA* mutant *Corynebacterium glutamicum* culture (see Methods, page 1661) and collections of media, which contains accumulated amino acids inherently (see Methods, page 1663). Thus, Tzvetkov et al. teach processes that

meet all the limitation of the instant claims. This rejection can be overcome by amending claims 49 and 50 to find a support in the claimed priority document.

### ***Conclusion***

22. Claims 46-64 are rejected for the reasons identified in the numbered sections of the Office Action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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16 February 2006

  
**KATHLEEN M. KERR, PH.D.**  
**SUPERVISORY PATENT EXAMINER**